

CLAIMS

1. A storage container for a weakly acidic solution formulation containing human growth hormone, comprising:

a cylindrical container having a first opening and a second opening, and an internal cavity connecting the first opening and second opening;

a first sealing member for sealing said first opening; and

a second sealing member provided in the internal cavity of said cylindrical container, such as to be capable of moving along said internal cavity while forming a continuous seal in a circumferential direction with an inner wall which forms this internal cavity, thereby forming an enclosed space with said first sealing member for containing the weakly acidic solution formulation containing human growth hormone;

said storage container for a weakly acidic solution formulation containing human growth hormone being characterized in that:

said second sealing member is composed of a type of rubber such that after such a second sealing member is immersed in 1 ml of a buffer solution containing a surfactant and having a pH of 5.5-6.5 and stored while shaking at a temperature of 25 °C for 1 week, the elution rate of polyvalent metal ions in said buffer solution as measured by atomic absorption spectrophotometry is 50 ppm or less.

2. A storage container for a weakly acidic solution formulation in accordance with claim 1, wherein said first sealing member is composed of a type of rubber such that after such a first sealing member is immersed in 1 ml of a buffer solution containing a surfactant and having a pH of 5.5-6.5 and stored while shaking at a temperature of 25 °C for 1 week, the elution rate of polyvalent metal ions in said buffer solution as measured by atomic absorption spectrophotometry is 50 ppm or less.

3. A storage container for a weakly acidic solution formulation in accordance with either claim 1 or 2, wherein the elution rate of said polyvalent metal ions is 20 ppm or less.

4. A storage container for a weakly acidic solution formulation in accordance with any one of claims 1-3, wherein said polyvalent metal ions are zinc ions or aluminum ions.

5. An injection cartridge for a weakly acidic solution formulation containing

5 human growth hormone, comprising:

a cylindrical container having a first opening and a second opening, and an internal cavity connecting the first opening and second opening;

10 a first sealing member for sealing said first opening, having a thickness such as to be capable of being punctured by a syringe needle; and

15 a second sealing member provided in the internal cavity of said cylindrical container, such as to be capable of moving along said internal cavity while forming a continuous seal in a circumferential direction with an inner wall which forms this internal cavity, thereby forming an enclosed space with said first sealing member for containing

20 the weakly acidic solution formulation containing human growth hormone;

said injection cartridge for a weakly acidic solution formulation containing human growth hormone being characterized in that:

25 said second sealing member is composed of a type of rubber such that after such a second sealing member is immersed in 1 ml of a buffer solution containing a surfactant and having a pH of 5.5-6.5 and stored while shaking at a temperature of 25 °C for 1 week, the elution rate of polyvalent metal ions in said buffer solution as measured by atomic absorption spectrophotometry is 50 ppm or less.

30 6. An injection cartridge for a weakly acidic solution formulation containing human growth hormone in accordance with claim 5, wherein said first sealing member is composed of a type of rubber such that after such a first sealing member is immersed in 1 ml of a buffer solution containing a surfactant and having a pH of 5.5-6.5 and stored while shaking at a temperature of 25 °C for 1 week, the elution rate of polyvalent metal ions in said buffer solution as measured by atomic absorption spectrophotometry is 50 ppm or less.

40 7. A method for storing a weakly acidic solution containing human growth hormone, comprising steps of:

30 preparing a cylindrical container having a first opening and a second opening, and an internal cavity connecting the first opening and second opening;

45 providing a rubber stopper in the internal cavity of said cylindrical container, such as to be capable of moving along said internal cavity while forming a continuous seal in a circumferential direction with an inner wall which forms this internal cavity, thereby forming a space with said first sealing member;

50 filling said space with the weakly acidic solution formulation containing human growth hormone; and

5 sealing said first opening with a cap;

said method for storing a weakly acidic solution containing human growth hormone being characterized in that said rubber stopper is composed of a type of rubber such that after such a rubber stopper is immersed in 1 ml of a buffer solution
10 containing a surfactant and having a pH of 5.5-6.5 and stored while shaking at a temperature of 25 °C for 1 week, the elution rate of polyvalent metal ions in said buffer solution as measured by atomic absorption spectrophotometry is 50 ppm or less.

15 8. A method for storing a weakly acidic solution containing human growth hormone in accordance with claim 7, comprising a step of adding a polyvalent metal ion
10 chelating agent to the weakly acidic solution containing human growth hormone.

20 9. A sealing member for a storage container for a weakly acidic solution formulation, the sealing member comprising:
15 a type of rubber such that after the sealing member is immersed in 1 ml of a buffer solution containing a surfactant and having a pH of 5.5-6.5 and stored while
25 shaking at a temperature of 25 °C for 1 week, the elution rate of polyvalent metal ions in said buffer solution as measured by atomic absorption spectrophotometry is 50 ppm or less.

20 10. The sealing member of claim 9 wherein the elution rate of said polyvalent metal ions is 20 ppm or less.

35 11. The sealing member of claim 9 wherein said polyvalent metal ions are zinc
25 ions or aluminum ions.

40 12. A process for determining whether a sealing member is suitable for use in a storage container for a weakly acidic solution formulation containing human growth hormone, the process comprising the steps of:
30 (a) immersing the sealing member in 1 ml of a buffer solution containing a surfactant and having a pH of 5.5-6.5;
45 (b) storing the immersed sealing member at a temperature of 25 °C for 1 week;
(c) simultaneously with step (b) shaking the immersed sealing member
35 at a temperature of 25 °C for 1 week; and
50 (d) measuring the elution rate of polyvalent metal ions in said buffer

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solution.

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13. The process of claim 12 wherein step (d) is performed by atomic absorption spectrophotometry.

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14. The process of claim 12 further comprising a step (e) of determining that the sealing member is suitable if the elution rate measured in step (d) is 50 ppm or less.

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15. The process of claim 12 further comprising a step (e) of determining that the sealing member is suitable if the elution rate measured in step (d) is 20 ppm or less.

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16. The process of claim 12 further comprising a step (e) of adding a polyvalent metal ion chelating agent to the weakly acidic solution containing human growth hormone.

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